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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,184	11/17/2003	George W. Muller	501872-999056	3369

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,184	MULLER ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 24-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 17 AND 24-32 ARE PRESENTED FOR EXAMINATION

On October 3, 2007, a request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action dated November 20, 2006 has been withdrawn pursuant to 37 CFR 1.114.

Applicants' amendment filed February 20, 2007 has been entered. In light of Applicants' remarks, the claim rejection under 35 U.S.C. § 112, first paragraph, as maintained in the Office action dated November 20, 2007, has been overcome and thus is *withdrawn*.

Claim Objection

Claim 24 is objected to because "a patient" informally references the patient of claim 17. In order to overcome this objection, "a patient" in claim 24 should be amended to read ---the patient--- or ---said patient---.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17 and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller, (U.S. Patent No. 5,877,200, cited in the IDS filed September 22, 2004 as reference "A53").

Muller teaches a method for treating a variety of diseases associated with tumor necrosis factor (TNF)-α which comprises administering to a patient, including mammals, (col. 11, lines 20-23), a therapeutically effective amount of 3-(3,4-dimethoxyphenyl)-3-(1-oxo-isoindolin-2-yl)-propionamide, (Example 42 at col. 42 and Examples 105-106 at col. 44). The patentees also teach the nexus between TNFα and phosphodiesterase (PDE)-type 4, (col. 4, lines 3-25). Further, the patentees disclose that the compounds of their invention may be administered in form having an optical purity of >95%, (i.e., enantiomerically pure), and provide for the - isomer in teaching that either of racemates can be administered individually, (col. 11, lines 29-45).

The patentees also disclose that in addition to administering a compound according to their invention, additional therapeutic agents may be administered and may be selected from classes of agents including, but not limited to antibiotics, steroids, "etc" (col. 10, lines 55-57).

The patentees generally teach one of ordinary skill in the art that "many inflammatory, infectious, immunological or malignant condition" may be treated, (col. 3, lines 22-25). The diseases/conditions which the patentees specifically disclose as being amenable to treatment include, but are not limited to, septic shock, sepsis, endotoxic shock, hemodynamic shock, sepsis

syndrome, post ischemic reperfusion injury, malaria, mycobacterial infection, meningitis, psoriasis, congestive heart failure, fibrotic disease, cachexia, graft rejection, cancer, autoimmune disease, opportunistic infections in AIDS, rheumatoid arthritis, rheumatoid spondylitis, osteoarthritis, other arthritic conditions, Crohn's disease, ulcerative colitis, multiple sclerosis, systemic lupus erythrematosis, ENL in leprosy, radiation damage, and hyperoxic alveolar injury, (col. 3, lines 25-35).

The patentees further teach that the compounds of their invention may be administered at dosages which are titrated to the particular age, weight and general physical condition of the patient, (col. 10, lines 65-67). General dosage amounts of from 10 to about 500 mg/day, as needed, in single or multiple daily administrations are further disclosed, (col. 10, line 68 - col. 11, line 2). The patentees further disclose varying the dosage amount by increasing the amount by 50% per week if necessary to achieve the desired therapeutic effect (col. 11, lines 10-13).

The patentees further disclose that the compounds of their invention may be administered by a variety of routes including, but not limited to oral, rectal, parenteral (col. 10, lines 52-64) and topical, (col. 11, lines 14-16).

The differences between the above and the claimed invention lies in that the patentees fail to duplicate the presently claimed listing of diseases which may treated or the presently claimed dosage ranges.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because the patentees provide generic teachings relating to the types of diseases which may

treated and the variation of dosage amounts. The determination of the specific diseases and dosage amounts, given the level of skill in the art and the broad instructive disclosure provided by the patentees, would have been well within the purview of the skilled artisan and it is not seen that Applicants' listing of diseases or dosage ranges are unexpected over or inconsistent with the disclosure of the patentees.

Accordingly, for the above reasons, the claims are deemed properly rejected.

None of claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

November 23, 2007